

REMARKS

1. Rejection of Claims 3, 7, 11, 15, 19, 23, 27, 31 and 35 under 35 U.S.C. 112, second paragraph.

Claims 3, 7, 11, 15, 19, 23, 27, 31 and 35 were rejected under 35 U.S.C. 112, second paragraph for the reasons of record. Specifically, the Examiner argued that the limitation of "prodrug of estradiol metabolite" renders the claim indefinite because it is not clear what compounds are encompassed by the claims.

Applicants respectfully reassert the arguments presented in the response to the previous office action that (1) the term is clearly defined in the specification and (2) Applicants are entitled to rely on the common and ordinary usage of the term. Further, Applicants argue that the Examiner's position that "structural or chemical characteristics" associated with the term are required in order to define the scope of the claim is a misapplication of 35 U.S.C. 112, second paragraph. That is, it is the Applicants' position that ANY structure that falls within the functional definition provided by the specification (i.e. the specification defines a prodrug as a compound that releases an estradiol metabolite) falls within the claims and such scope is clear and definite to one of skill in the art.

However, in order to expedite allowance of claims Applicants have canceled Claims 3, 7, 11, 15, 19, 23, 27, 31 and 35 without prejudice or disclaimer of the subject matter thereof, rendering the rejection moot.

2. Rejection of Claims 1-36 under 35 U.S.C. 103(a)

Claims 1-36 were rejected under 35 U.S.C. 103(a) as obvious over US2003/0027751 ('751) and US2001/0056068 ('068), for the reasons of record. Applicants respectfully traverse the rejection.

Initially, Applicants respectfully assert that the office action over states the disclosure of the '751 reference. Specifically, the Examiner cites the '751 reference as teaching that 2-methoxyestradiol is useful in treating pulmonary hypertension (paragraphs 0175 and 0179). Paragraph 0175 teaches that 2-methoxyestradiol is known to reduce naturally occurring anti-angiogenic factors and thus could be co-administered with the angiogenic fusion protein of the '751 invention to aid in the angiogenic effect of the fusion protein. Paragraph 0179

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simply lists the various ailments that might be treated by the angiogenic fusion protein of that invention, one of which is pulmonary hypertension.

The '751 reference contains no teachings whatsoever regarding the usefulness of 2-methoxyestradiol in and of itself for treating any disease, outside of its ability to block or reduce anti-angiogenic factors. Accordingly, the '751 application cannot be fairly interpreted as teaching 2-methoxyestradiol is useful in treating pulmonary hypertension.

Further, Applicants reiterate their position presented in response to the previous office action regarding the teachings of the '068 application. The '068 application teaches that estradiol is beneficial in treating pulmonary hypertension via increasing nitric oxide. The '068 application does not contain any teachings regarding estradiol metabolites, as described and claimed in the present invention.

As evidenced by the Xiao et al reference, which was made of record by the Examiner in the previous office action, at the time of filing the present invention, one of skill in the art was taught that estradiol, but not estradiol metabolites such as 2ME or 2HE, increased nitric oxide (see Xiao et al. Figure 1). Therefore, contrary to the surprising findings of the present invention, one of skill in the art was taught that estradiol metabolites would not be effective in a nitric oxide deficiency disease such as pulmonary hypertension.

In view of the lack of teaching in the cited references regarding the beneficial effects of estradiol metabolites, and the teaching away of Xiao et al Applicants argue that one of skill in the art would have neither motivation nor a reasonable expectation of success that estradiol metabolites would be useful in the treatment of a nitric oxide deficiency disease. Applicants further assert that the combined references fail to teach or suggest every element of the claimed invention as required for a rejection under 35 U.S.C. 103(a).

In view of the foregoing, Applicants respectfully request withdrawal of the rejection of Claims 1-36 under 35 U.S.C. 103(a).

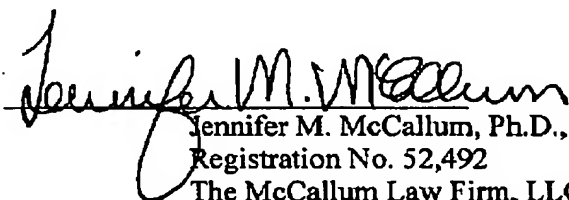
Concluding Remarks

In view of the foregoing, Applicants respectfully submit that all rejections under 35 U.S.C. 112 and 35 U.S.C. 103(a) have been overcome. Accordingly, Applicants believe that Claims 1-36 are in condition for allowance.

Respectfully Submitted,

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Date



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